TAB 12C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME 23
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 9, 2021

A. I believe that -- I don't know what DEA is doing, but I believe that Congress actually codified that regulation.

Q. Do you know if DEA has proposed a rule making process to amend this regulation?

A. I don't know.

Q. Okay. You talked about having responsibility for promulgating regulations, correct?

A. That's correct.

Q. You never amended this regulation on your watch, did you?

A. No, I did not.

Q. Did you ever try internally to add language to this regulation that would go to any of the points you've talked about in your testimony, do not ship, explain why an order is being reported, only report truly suspicious? Did you ever attempt internally to amend the regulation on any of those grounds?

A. No, I did not.

Q. Now, I want to come to an idea I just touched on, which is do you remember talking about explaining -- distributors explaining why suspicious orders were being reported? Do you remember giving --

A. Can you repeat that one more time?

Q. Sure. You gave testimony on several times that you weren't getting explanations for why suspicious orders were

being reported. Do you remember saying that?

A. Yes.

Q. And I'll come back to what the distributors actually did explain, but before I do that, I want to go to this regulation as left unamended by you. There's no language in this regulation saying explain why you consider it to be of unusual size, deviating substantially from a normal pattern, or of unusual frequency, correct?

A. That is correct.

Q. And you never sought to amend the regulation to require such an explanation, correct?

A. We did not amend the regulation, that's correct.

Q. All right. I want to follow up on testimony you had about there not being any policy change at DEA when you came into place and I want to focus on this 2005 to 2008 window, if that's okay.

A. Okay. Yes, sir.

Q. And do you have the understanding that, as the Court has heard through testimony, by 2008 every defendant in this case had a policy in place that involved blocking flagged orders? Do you have that understanding?

A. From my knowledge at DEA?

Q. Yes, sir.

A. Yes.

Q. Okay. And you agree that if an order is blocked the

medicine cannot be diverted?

A. If the order is blocked, the medicine can't go downstream.

Q. And it can't be diverted, correct?

A. That's correct.

Q. And from your time at DEA you can't identify any orders in Huntington or Cabell County that you believed that DEA should have been blocked by one of the defendants but were not, correct?

MR. ACKERMAN: Objection, Your Honor, and this goes to the scope of Mr. Rannazzisi's deposition. The words "West Virginia" don't appear in the deposition transcript, so --

THE COURT: Overruled. This is cross examination. I'll allow it. Go ahead.

THE WITNESS: No, I have not reviewed any documents related to West Virginia.

BY MR. SCHMIDT:

Q. So, let me focus still on this time period when you came in from 2005 through 2008 and even into 2009. Am I correct that before 2006 and 2007 you have no firsthand knowledge about whether the DEA was aware that it had earlier been standard practice in the industry to file Suspicious Order Reports while continuing to ship product? Am I correct you have no firsthand knowledge on that point?

A. Could you -- what do you feel is firsthand knowledge?

Q. Whatever you consider firsthand knowledge. And if it helps to show you your testimony, I can show you your testimony.

A. I have no -- I have no direct knowledge except for what my staff told me.

Q. And I'm not going to ask you about discussions because of hearsay. You've talked about effective controls against diversion; you remember that, right?

A. Yes.

Q. Am I correct that prior to the Fall of 2005 and since 1970, you can't recall any type of document or guidance where the distributors were told to do certain things that were related to maintaining effective controls against diversion?

A. That's correct.

Q. And am I correct you've not watched the testimony in this case to see testimony from individual witnesses at individual companies where they said prior to 2008 if they saw something that they thought was likely to be diverted they would block it? Have you seen that testimony?

A. I have not seen that testimony, no.

Q. Do you know what the practice was prior to 2005 with the defendants in this case when they saw an order that was likely to be diverted?

A. Yes.

Q. In conjunction with CCD, has notified in writing, all distributors of their responsibility to immediately report all, quote, "suspicious orders", quote. Do you see that?

A. Yes.

Q. A suspicious order is an order, which, when received by a registrant and in accordance with 21 CFR 1301.74, that's the regulation you were looking at, correct?

A. Yes.

Q. The registrant determines to be suspicious. Do you see that?

A. Yes.

Q. And then it says the registrant -- and it's bolded and underlined for emphasis -- does not fill the order but reports same to their local DEA Office. Do you see that emphasized language, does not fill the order?

A. Yes.

Q. It then says -- that was new to this interim version of the manual, that bold underscore language, correct?

A. Does not fill?

Q. Yes.

A. It's just -- it's just an update of the previous language.

Q. That language does not appear in the prior manual as applied to a single order, correct?

A. I would have to go back and look.

MR. SCHMIDT: Why don't we -- why don't we help Mr. Rannazzisi out. Could we do a side-by-side and can we put P -- on the left side, could we put P-8861 on the left? If it's possible to switch those so that P-8861 is on the left, please.

And go to Page 12 on the left, please. And if we can blow up that language a little bit.

And then on the right, can we put DEF-WV-3842, Page 3? And if we could blow up that suspicious order reporting.

And let's highlight, if we could, on the bottom does not fill the order, singular.

BY MR. SCHMIDT:

Q. Do you see that language?

A. Yes.

Q. That's new to the 2009 update, correct?

A. That's new to the manual.

Q. Okay. And then the manual, the 2009, goes on to say Excessive Purchase Reports from registrants, reports of unusual size, will no longer be accepted by the DEA, correct?

A. That is correct, yes.

Q. And that bold underline language in the second sentence, will no longer be accepted, it doesn't say they've never been accepted. It says they will no longer be

accepted, correct?

A. Yes. I can give you an explanation, if you would like, why it says that.

Q. And it says any firm still reporting excessive purchases. So you knew firms were doing that, right?

A. Uh-huh.

Q. Will be informed of the OD directive and instructed to immediately report, quote, "suspicious orders", quote. Do you see that?

A. Yes. And the reason that was placed there was because even after we instructed the firms in the letters and even though that we had the face-to-face meetings they were still sending Excessive Purchase Reports and we decided that instead of continuing to receive these Excessive Purchase Reports, which were not Suspicious Order Reports, and we told them those are not Suspicious Order Reports, to just stop sending the Excessive Purchase Reports totally.

Even though they knew that those weren't Excessive Purchase Reports they continued to send them. The only way to stop it is just to tell them to stop it. That's why that provision was put in there.

Q. That language does not appear in the Diversion Investigators Manual from before your tenure, correct?

A. It doesn't appear to appear, yes.

Q. And let's just show exactly what we're looking at in

the harms of diversion; correct?

A. That is correct.

Q. In fact, one of the DEA's core functions is to prevent the diversion of controlled substances into illicit channels; correct? That's a core function of the DEA?

A. Yes.

Q. At the same time, and I think you talked about this in some of your testimony yesterday particularly on quota, DEA has a mission to ensure an adequate and uninterrupted supply of controlled substances; correct?

A. That's correct.

Q. And you agree that it's vital that an adequate and uninterrupted supply of pharmaceutical controlled substances be available for effective patient care?

A. Yes.

Q. It's a public health concern when pharmacies cannot dispense legitimate pharmaceutical controlled substances to patients; correct?

A. To legitimate patients, yes.

Q. There can be no doubt that drug shortages adversely affect the public health; correct?

A. That's, that's obvious, yes.

Q. All right. From your experience, you agree that when it comes to the supply of prescription opioids, supply does not drive demand?

A. Supply does not drive demand.

MR. ACKERMAN: Your Honor, while Mr. Schmidt is writing, if it's at all possible for the Court to move that to our screens, then I don't need to stand here with my friends.

MR. SCHMIDT: Yeah, no objection, of course.

THE COURT: Yeah. Just find a good place there, Mr. Ackerman.

MR. SCHMIDT: I'm sorry. Before you switch it, the problem is that we may need to put up documents on the individual screen.

MR. ACKERMAN: All right. I'll find a chair over here.

MR. SCHMIDT: There's an empty one at my table.

(Laughter)

BY MR. SCHMIDT:

Q. Going back to this point, when it comes to demand for prescription opioids, that comes not from supply but from prescribing and dispensing in hospitals; correct?

A. No, not necessarily. Demand also -- when we're talking about quota, it has things to do with research and development, validation, export, things like that.

Q. When it comes to -- let me rephrase. When it comes to demand, demand comes from things like prescribing, hospitals, research and development, export; correct?

A. For that portion of the quota. Well, yeah, total, yes.

Q. The demand is driven by patient care and patient needs; correct?

A. A large part of the quota is patient needs.

Q. Not by supply; correct? I didn't hear if you answered. I apologize, sir. Not by supply; correct?

A. No, supply is not what drives demand.

COURT REPORTER: I'm sorry?

THE WITNESS: Demand drives the quota.

BY MR. SCHMIDT:

Q. Your understanding of what drives demand for opioids is appropriate medical treatment; correct?

A. Yes, if -- appropriate medical treatment, yes.

Q. And prescription opioid levels in turn -- prescription opioid levels in turn are based on the presumption that medical need is legitimate; correct?

A. Yes. Appropriate medical treatment does drive some of the demand, yes.

Q. And just because you have a supply of prescription opioids does not mean the supply must be used; correct?

A. That's correct.

Q. Correspondingly, reducing supply doesn't necessarily reduce demand; correct?

A. That's correct.

Q. All right. Now, in terms of supply level, you never

provided guidance at DEA to tell companies that for a given dose or type of prescription opioid if they see doses above that level, they should investigate, did you?

A. I personally didn't.

Q. Okay.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I've passed you a document marked P-23594-001. Do you know what this document is?

A. Yes. I believe these are the summary reports that we put on the DEA website.

MR. SCHMIDT: I move this into evidence, Your Honor.

THE COURT: Yes.

MR. ACKERMAN: No objection.

THE COURT: Did you move its admission?

MR. SCHMIDT: I did, Your Honor.

THE COURT: And there's no objection; right?

MR. ACKERMAN: No objection.

THE COURT: I was reading it and I wasn't paying attention. It's admitted.

BY MR. SCHMIDT:

Q. All right. If we look at the cover of this document, do you see it says "Department of Justice"?

And it's on your screen as well, just not on the big screen.

A. Yes.

Q. And it says "ARCOS Report 4." Do you see that?

A. Yes.

Q. And it says reporting period January, 2010 to December, 2010. Do you see that?

A. Yes.

Q. And this is, this is that portion of the ARCOS data the DEA reported to the public; correct?

A. Yes.

Q. And I've chosen this period of time because there's been a focus on this period of time in terms of a high level, or purportedly high level of prescription opioids during this time period.

So let's -- having said that, let's look at Page 21 of this report. Actually, let's start with Page 18. I apologize.

And if we look at -- tell me when you're there, sir.

A. I believe I'm there.

Q. Okay. If you look at the left-hand side about two-thirds of the way down, and if you can pull it up a tiny bit, just pull up the screen a tiny bit. There we go.

It says U.S. grams per hundred thousand, Drug Code 9143, drug name hydrocodone [sic].

Do you see that?

A. Yes.

Q. Do you have an understanding that this is the DEA reporting the average grams per hundred thousand people for different states for oxycodone?

A. Based on ARCOS, yes.

Q. Correct?

A. It's the amount of drugs that ARCOS, on an ARCOS analysis has gone into these states per 100,000.

Q. And if we look at West Virginia, West Virginia is 9. Do you see that?

A. Yes.

Q. Let's go to 21. And, very quickly, do you see that 21 reports the same data for hydrocodone? This time West Virginia at this point in time is number 7. Do you see that?

A. Yes.

Q. When you were at DEA, did you ever issue guidance to distributors, the healthcare community, doctors that these levels were too high?

A. No, I did not.

Q. Are you aware that the DEA also publishes this data at the zip code level?

A. I'm sorry?

Q. At the zip code level.

A. Yes, uh-huh.

MR. SCHMIDT: May I approach?

THE COURT: Yes. You should have bought stock in International Paper, Mr. Schmidt.

MR. ACKERMAN: At some point, Your Honor, I'm sure someone is going to object on behalf of the earth.

MR. SCHMIDT: Someone should. I'm happy to do less.

BY MR. SCHMIDT:

Q. This is a lot of paper for a little point.

Do you see that this is 23591 and it's a similar retail drug summary report, but this time by zip code within the state? Do you see that?

A. Yes.

MR. SCHMIDT: We move this into evidence, Your Honor.

THE COURT: Any objection?

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. Let's look at Page 354, please. Do you see that on Page 354 -- I thought it said oxycodone on this page. I'll represent to you that this is the oxycodone levels. You can flip back in the report to confirm that.

Do you see the report of the oxycodone levels by zip

code on Page 354?

A. Yes.

Q. And if we look at zip codes 255 and 257, do you see those zip codes?

A. Yes.

Q. And I'll represent to you that those zip codes include Huntington and Cabell County, but they also include additional areas. Is that something you were aware of?

A. No.

Q. Did DEA ever issue any guidance in connection with issuing a report like this at any point in time to healthcare providers, manufacturers, distributors, pharmacies that specific levels at the zip code level were too high?

A. No. DEA would not issue something like that.

Q. Did they ever say certain levels merited investigation?

A. No. The reason this is put on there is to help healthcare providers, public health officials, law enforcement, different organizations knowing what's going into their systems. That's why it's on the DEA website.

Q. That was the intent, to let entities like the City of Huntington and Cabell County know exactly what was going into their communities?

A. Health departments, state health departments, things like that. We wanted to get it out there about exactly

population wise how much drug is going into the areas.

Q. So that they could act as appropriate if they deemed it appropriate?

A. The information was presented for their -- whatever they deemed appropriate.

Q. Okay. I want to talk about some of the participants now in the closed system that you touched on with the Court yesterday and the day before.

Anyone who handles a controlled substance has to be registered with the DEA; correct?

A. Except for nurses and pharmacists.

Q. Nurses have to operate under the direction of doctors; correct?

A. Or hospitals.

Q. Or hospitals. And pharmacists have to be affiliated with a pharmacy that's registered; is that correct?

A. Yes, uh-huh.

Q. And that DEA registration includes prescribers; right?

A. Yes.

Q. Prescribers can only write prescriptions for prescription opioids if they're licensed with their state but also if they're registered with the DEA; correct?

A. Yes.

Q. Did you have an understanding when you were at the DEA as to why there's a separate requirement for DEA

registration in addition to the requirement that they be licensed by the state?

A. So a DEA registration authorizes them to have a -- to handle controlled substances. The state registration, because they're licensed to practice medicine or whatever they're practicing, and also there's a separate state license for controlled substances but -- in some states.

So there's -- it's a two-part system. You've got to be registered by the state. The state has to grant you a license. And then DEA will come and grant you their license.

Q. My question was a little different, sir. My question was why is there a DEA requirement of a separate DEA registration in order to prescribe controlled substances, if you know? Why not just have the state requirement?

A. Because under the Controlled Substances Act it's required.

Q. Do you know why?

A. Yeah, because the federal government wants to ensure that controlled substances under the Act are being handled appropriately.

Q. You understand that registration had to be renewed every three years?

A. Yes.

Q. And just so -- actually, I'll skip moving in the

regulation.

Did you have an understanding when you were at DEA as to why prescribers weren't simply given a lifetime registration from DEA, why they had to be renewed every three years?

A. To ensure that they're appropriately licensed and that they did not have anything in their backgrounds during that three-year period that could warrant them, you know, disqualifying them from getting a license, a DEA registration.

Q. I'm going to show you P-4215 if I could. I just misread it. I apologize. It's P-42145.

MR. SCHMIDT: May I approach, Your Honor?

BY MR. SCHMIDT:

Q. Mr. Rannazzisi, do you recognize this as a DEA regulation regarding prescriptions for controlled substances?

A. Yes.

MR. SCHMIDT: We move this into evidence, Your Honor.

THE COURT: Any objection?

MR. SCHMIDT: P, Plaintiffs' 42145.

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MR. SCHMIDT:

Q. In this regulation in the second sentence it states, "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner."

Do you see that language?

A. Yes.

Q. And then it refers to a corresponding responsibility with the pharmacist who fills the prescription; correct?

A. That's correct.

Q. And only a DEA registered practitioner may make the determination if a controlled substance is medically necessary; correct?

A. For a particular patient.

Q. Yes.

A. For prescribing, yes.

Q. And a distributor cannot make the determination if a controlled substance is medically necessary for a particular patient; correct?

A. Yes. And we've never asked a distributor to do that.

Q. Fair. In fact, yesterday you testified that you were not asking distributors to become doctors and figure out what's legitimate and what's not; correct?

A. That's correct.

Q. Yesterday you testified that you never required distributors to look at what doctors were doing, questioning

a doctor's prescribing habits; correct?

A. That's correct.

Q. Why are DEA registered practitioners the only ones who can make the determination that a medication is appropriate for an individual patient?

A. Because they have to make a determination that the medication that they're prescribing meets the needs, medical needs of that particular patient. They're seeing that patient. No one else is.

Q. Okay. Was there ever an occasion you know of where you or someone at DEA told one of the distributors in this case that they should stop supplying to a pharmacy in Huntington or Cabell because of a DEA registered doctor whose prescriptions were being filled at that pharmacy?

A. I've never done that, and I don't know of anybody among the staff that has when I was there.

Q. You would agree with me that -- and I think you talked about some of these statistics yesterday. I just want to make sure we're on the same page.

During your time at DEA, 99.5 percent of prescribers were not over-prescribing; correct?

A. Yeah, we used that number. We generally used 99 percent but we've gone to .5.

Q. And I don't want to quibble, but because I've written 99.5 on the board, do you want to see your congressional

testimony where you said that?

A. That's fine.

Q. You don't take issue with it; right?

A. We've used 99 percent too. It just depends on when we're talking.

Q. Yeah, understood. And that's what I want to go to next. You've actually said 99 percent of doctors are perfect. Correct?

A. Yeah, I've said that they're doing things appropriately, yes.

Q. That they're perfect; correct?

A. I don't recall saying "perfect," but I may have during one presentation.

MS. SINGER: Objection, Your Honor. I don't think what Mr. Schmidt wrote is what Mr. Rannazzisi just testified.

MR. SCHMIDT: Let me see if I can cure that, Your Honor.

BY MR. SCHMIDT:

Q. Defense West Virginia 620. Do you remember being asked about giving congressional testimony at various points in time, Mr. Rannazzisi?

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

THE WITNESS: Yes.

MR. SCHMIDT: If there's no objection, we'll start doing excerpts on these bigger documents. It does seem a waste to do all this for a small part at this point.

BY MR. SCHMIDT:

Q. If we look at Defense West Virginia 620, it's a hearing before a House of Representatives Committee, March 1st, 2012. Do you see that?

A. Yes.

Q. And then if we go to -- I'm using the numbers in the lower left corner, Page 98. You'll see various comments from you, including a larger one in the top half, right barely above the top half of the page. Do you see that?

A. On page -- which page?

Q. Page 98 in the lower left-hand corner.

A. Yes, I've got it.

Q. And if you look at the second sentence there that begins "the problem," do you see that? Do you see where you say, "The problem is that the doctors continue," and then you stop, "not all doctors, 99 percent of the doctors are perfect."

Do you see that you said that before Congress?

A. Maybe I'm not on the right page then. What's the page on top?

Q. The page on top is 94.

A. Okay. I'm there.

Q. And it's the third quote from you on the page right before the halfway mark.

A. Okay. I see it. I see it.

Q. Do you see where you said to Congress 99 percent of the doctors are perfect? Do you see that?

A. Yes.

Q. Were you trying to be accurate and correct in your testimony to Congress?

A. I was giving an estimate on what DEA has said in the past.

Q. Okay.

THE COURT: Do you still object, Ms. Singer?

MS. SINGER: I don't think it's worth the objection, Your Honor, so I withdraw the objection.

MR. SCHMIDT: Thank you.

BY MR. SCHMIDT:

Q. You repeatedly stated, including to Congress throughout your tenure, that the overwhelming majority of prescribing in America is conducted responsibly. Correct?

A. Yes.

Q. And during your tenure, you also said that the DEA recognizes that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose in the usual course of professional practice;

correct?

A. Where, where did I say that? I've got to go back and look at that.

Q. Okay. Let's take a look at that.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. This is a statement from the Federal Register DEA -- while you were at DEA. Do you see that? September 6th, 2006?

A. Yes.

Q. Okay.

MR. SCHMIDT: We move this into evidence, Your Honor, Defense West Virginia 3076.

THE COURT: Any objection to this one?

MR. SCHMIDT: Actually, this is in evidence. Nevermind.

THE COURT: Oh, it's in evidence.

MR. SCHMIDT: I'm sorry.

BY MR. SCHMIDT:

Q. Let's go to the second page.

A. Uh-huh.

Q. On the second page in the upper left corner it says, "Drug Enforcement Administration." And it says "Action: Policy Statement." Do you see that this is a policy

of doctors acting improperly, and I want to direct your attention to that.

Could we go to Page 5 of this document. And tell me when you're there.

Let's cull up the right-hand column, just the heading.

A. Okay. I'm on Page 5.

Q. Can we cull up Page 5, Defense West Virginia 3076, so we're all looking at the same thing. Is it available to put up on the screen? Thank you.

And while we do, let me read the title in the record, the heading -- I'm sorry -- of this subsection.

It says, "The number of physicians who prescribe controlled substances in violation of the CSA --" and now we see it on the screen -- "is extremely small and there is no DEA crackdown on physicians."

Do you see that in this policy statement that when it comes to the physicians who prescribe controlled substances in violation of the CSA, that is extremely small? Do you see that?

A. Yes, as compared to the patient population, yes, the physician population, prescriber population, yes.

Q. That's a true statement; right?

A. Yes.

Q. And it then goes on to characterize that. It has that "overwhelming majority" language you and I have talked

about. DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes.

Do you see that?

A. Yes.

Q. In fact, the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by federal or state law enforcement officials. Do you see that?

A. Yes.

Q. And is that a true statement?

A. Yes.

Q. And then you quantify actions against doctors in the italicized sentence, if we can scroll down in this column, please.

Do you see a little further down there's an italicized sentence? Do you see that?

A. Yes.

Q. "In any given year, including 2005, fewer than one out of every 10,000 physicians in the United States (less than .01 percent) lose their controlled substance registrations based on a DEA investigation of improper prescribing."

Did I read that correctly?

A. Yes.

Q. Is that accurate that in a given year less than

.01 percent of physicians in the United States lose their controlled substance registration based on a DEA investigation of improper prescribing?

A. Back in 2005 and prior to, yes.

Q. Was that true in 2007 when you gave the same testimony before Congress?

A. I'm not sure in 2007 if that's true or not. I would, I would guess that the numbers -- I just don't recall. But, but this is specific to prior to 2005. So if there's some other document or -- I've looked at it, but I just don't recall saying that except for 99 percent of the prescribers. Generally, 99 percent of the prescribers are doing exactly what they're told to do.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: Actually, can we just put it up on the screen because it's impeachment? We have it here.

THE WITNESS: Thank you.

MR. SCHMIDT: You're welcome.

BY MR. SCHMIDT:

Q. I've passed you MC-WV-2172, testimony before House of Representatives Subcommittee on July 12th, 2007. Do you see that?

A. Yes.

Q. If you go to Page 11 in the bottom left-hand corner

you'll see a prepared statement from you read into the record. Do you see that?

A. Yes.

Q. And if you go to Page 12, the fifth full paragraph, generally speaking, do you see you again in July of 2007 saying, "In any given year DEA arrests less than .01 percent of the 750,000 doctors registered with the DEA for a criminal violation." Do you see that?

A. Yes. That's specific to a criminal violation.

Q. Okay.

A. That's what it says, a criminal violation.

Q. Okay.

A. It doesn't say anything about administrative actions.

Q. I'm not going to ask you about those further. Do you want me to take back any of those large documents?

A. I would love for you to take back some of these large document.

Q. That's the only time you'll ever say that to me. But the testimony, if you want to give me that, all the suspicious order reports, if you want to give me those.

A. Yes.

Q. All right. So if we go back to this 2006 policy statement from DEA, Defendants' West Virginia 3076, I want to go back to Page 5, please. And let's look at that italicized sentence we were highlighting.

Have you ever publicly identified what percentage of opioid prescriptions in a given year are written by this .01 percent versus the remaining 99.9 percent? Is that something you've ever quantified for the public?

A. No.

Q. Do you know if any of the doctors in Huntington or Cabell on your watch were in this .01 percent?

A. I do not know.

Q. And when you identified those .01 percent who lost their registrations on the other example were criminally prosecuted, did you make that determination just by looking at their prescribing levels or did you require more information?

A. Oh, it would require an investigation, a full investigation.

Q. Did you ever have a criteria that if a doctor fell within the top one percent, they would automatically be investigated in terms of their prescribing levels?

A. Doctors are investigated based on a specific set of facts. And after that, you know, we get into an investigative process.

Q. My question was simply was there ever --

A. I'm sorry. I said doctors investigated by specific -- it's fact-based, specific set of facts. So we don't investigate based on quantities.

Q. You answered my question. Thank you. You looked at a range of factors to determine --

A. A range of factors, yes.

Q. A range of factors beyond simply quantity; correct?

A. Yes, for doctors, yes.

Q. Yes. Now, the DEA made these statements about prosecutions being rare in the context of wanting to encourage doctors that they could prescribe prescription opioids as medically appropriate without being concerned about the DEA cracking down on them; correct?

A. We wanted to assure doctors that if they were prescribing appropriately, they would never have problems with DEA as long as they were prescribing for legitimate medical purpose in the usual course of professional practice.

Q. In fact, if we look at -- if we look at the document we were just looking at 3076-5, the policy statement, the language we were just looking at, the heading, Page 5, that heading says there is no DEA crackdown on physicians; correct?

A. I don't know where -- this is not --

Q. It's Page 5 on the right-hand side, the boldfaced heading.

A. Page 5, right-hand side.

Q. There is no crackdown -- no DEA crackdown on

physicians. That's what you were reassuring doctors of; correct?

A. Yes.

Q. And you've said in your testimony before Congress that doctors should not hesitate and should continue to provide patients with whatever treatment they feel appropriate as long as it's for a legitimate medical purpose and done in the usual course of medical practice; correct?

A. That's the standard, yes.

Q. And let's go to Page 6 in this document, Defense West Virginia 3076. In the upper left-hand corner it states, "It would be a disservice to many patients if exaggerated statements regarding the likelihood of a DEA investigation resulted in physicians mistakenly concluding that they must scale back their patient's use of controlled substances to levels below that which is medically appropriate."

That's a true statement; correct?

A. Back in 2006, yes.

Q. And just to be clear, there was an opioid crisis in 2006; correct?

A. There was, yes.

Q. Now, you gave specific guidance in this document; correct?

A. I'm, I'm not sure where -- if you point it to me, I'm more than happy to read it.

Q. We saw on Page 7, the language we were looking at, that this regulation or this rule making talked about people who supported this change. Do you remember we read that language into the record?

A. Yes.

Q. There were also people who opposed it, correct?

A. Yes. I'm sure there were. There were always people that opposed that.

Q. Let's look at that. Third paragraph from the bottom. It says appropriateness of this rule in view of the extent of prescription controlled substance abuse in the United States. Do you see that?

A. Yes.

Q. And some of the commentators who objected to the proposed rule, among those, quote, "many pointed to the alarming increase in prescription controlled substance abuse in the United States and resulting deaths and harm to the public welfare." Those were comments you received opposing this lengthening of the time that doctors could give prescription opioids for without seeing their patients, correct?

A. Yes.

Q. And then, if we go a little further up, it says possibility of increased pressure on prescribing practitioners and it talks about some commentators and the

second line at the end asserting practitioners might feel undue pressure to prescribe a 90-day supply of controlled substances at each office visit. Do you see that?

A. Yes.

Q. And this rule change was made at a time you were grappling with internet pharmacies, right?

A. Yes.

Q. This rule change was made at a time that you started to see a problem with rogue pain clinics, correct?

A. There were pain clinics out there at the time, yes.

Q. And just -- quick point on rogue pain clinics. Did you ever adopt a rule or a practice where you refused to register doctors if they were in pain clinics?

A. No.

Q. Why not?

A. Because there are pain clinics that are actually not rogue.

Q. Okay. Did you ever refuse to register pharmacies that dispensed prescriptions to doctors working at pain clinics?

A. Refuse or take action against?

Q. Refuse?

A. On an application, you're talking about?

Q. Yes, sir.

A. Well, I wouldn't know if they were taking pain clinic patients unless they were actually registered to be

pharmacies.

Q. That's with I'm taking about. The ones that are registered as pharmacies, did you ever condition their registration on them not supplying -- filling prescriptions from doctors at pain clinics?

A. Any pharmacy registration is conditioned on the fact that if you do fill prescriptions outside the usual course of professional practice and not for legitimate medical purpose and corresponding responsibility they could have their license removed.

Q. I'm asking a little bit of a different question, sir. Did you ever make a rule that you would not register them if they filled prescriptions from any pain clinic?

A. Of course not.

Q. For the same reason you just told me about, right?

A. Yes.

Q. Now, you touched on a topic I wanted to ask you about. You agree with me that the most common, most frequent method of obtaining a pharmaceutical controlled substance for non-medical use is through friends and family for free?

A. No. I -- repeat that question again. I want to make sure I got that one right.

Q. Sure. Of course. The most frequent method of obtaining a pharmaceutical controlled substance for non-medical use is friends and family for free?

A. That's -- that's not how congressional testimony works. Congressional testimony, you're presenting for the Administration for the Department of Justice.

Q. Is the answer to my question no, you never did?

A. No, I never did.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I have some excerpts of a 2013 presentation with your name on it. Do you see that on the cover slide regarding drug trends?

A. Yes.

Q. This is excerpts. If you go to Page 2 of the document --

MR. ACKERMAN: Objection, Your Honor. The problem we have is that defendants don't disclose their documents to us beforehand, so I don't know what's omitted from this document. So, I can't really object to it without finding it among a massive stack.

So, I would object to questioning regarding a portion of a document that, if we can work out the excerpts before the questioning, I think that's a different story. But to just present a witness with a self-selected cherry-picked excerpt of a document is improper.

MR. SCHMIDT: It's for impeachment, Your Honor.

THE COURT: Yeah, overruled.

BY MR. SCHMIDT:

Q. Do you see on Page 2 in this presentation you gave it says most frequent method of obtaining a pharmaceutical controlled substance for non-medical use, friends and family for free? Do you see that?

A. Yes.

Q. And do you know if you gave that -- made that statement at presentations more than once?

A. Yes. That was the Government's position.

Q. At any of those presentations did you say this is the Government's position, but my opinion, I disagree with it?

A. I wouldn't do that. That's not what we're allowed to do.

Q. Did you believe you were saying something false when you said this?

A. No. I -- as I said before, I didn't agree with it, but they had a survey to back it up, so I didn't have a choice but to go with it.

Q. Do you have any contrary data?

A. Yeah, our investigations.

Q. I mean like a study or a survey?

A. No. Just our investigations.

Q. And then the next slide says medicine cabinet and then problem, pharmaceutical controlled substance disposal. Do

you see that?
A. Yes.
Q. And then it says so many drugs in the household, why, and then it gives two reasons. Do you see that?
A. Yes.
Q. One is unreasonable quantities being prescribed. Do you see that?
A. Yes.
Q. And that refers to decisions being made by doctors, correct?
A. Yes.
Q. And do you believe that to be true, that some of the contributions to unreasonable levels of drugs in the household is unreasonable quantities being prescribed?
A. Yes.
Q. And just to be clear, what I understand you to be talking about here is that if -- and I think you touched on it in the context of that 90-day rule, that if you have a lot of opioids given to a given patient, someone else might use them?
A. Yes.
Q. Someone might take them. They might steal them. They might give them away. And that can be -- that is diversion?
A. Well, technically, yes.
Q. Every one of those is diversion, right, stealing,

Q. Were you aware at the time you referred doctors to State Medical Boards that statements like this were being sent by Medical Boards to doctors in at least 13 states?

MR. FARRELL: Objection, Your Honor. I think that misstates the testimony.

THE COURT: Overruled.

BY MR. SCHMIDT:

Q. Were you aware of that, sir?

A. No. Like I said, I wasn't aware that this book was being passed out by the Medical Boards.

Q. Okay. Go to Page 94 of the book. Do you see where there's a heading Federal Guidelines For Prescribing Controlled Substances? Do you see that heading?

A. Yes.

Q. And do you see -- if you just kind of scroll through there, do you see reference to the 2006 policy statement that you spent some time talking about earlier today?

A. Yes.

Q. And then if we continue on to the next page, Page 95, do you see that there's -- this came out before the 90-day rule we were just talking about was finalized, but do you see there's discussion of that rule being proposed?

A. Okay.

Q. Now, you said -- I'm not going to go through the rest of this book. I'm going to wrap up just with a couple of

questions.

When you were at DEA, you said you knew about this book. Did you ever -- you or your colleagues at DEA ever issue any kind of statement correcting anything you believed to be wrong in this book?

A. No. DEA did not get involved in medical practice.

Q. Do you see on the cover it says Federation of State Medical Boards?

A. Yes.

Q. On multiple occasions you've relied on guidelines from the Federation of State Medical Boards, correct?

A. Yes.

Q. And, in fact, one of those occasions is actually referring to distributors to the Federation of State Medical Boards, correct?

A. I'd have to see it.

Q. All right.

A. Referring to the internet pharmacy? I don't -- I would have to see what you're referring to.

Q. Fair enough. Let me help you out. Let's pull up P-1205, which is in evidence. I think it is a document you were shown, so you should have it in your stack, and it is the distributor slides. And let's go to Page 9 of that document.

And do you see that there is reference to -- in giving

guidance to distributors, there's reference to the Federation of State Medical Boards as something distributors can look to in understanding medical need?

A. Okay.

Q. That's guidance you gave to distributors about understanding medical need, correct?

A. Yeah. Because we're talking about the model guidelines of internet, yes.

Q. I want to touch very quickly on the other participants in the closed system starting with pharmacies. Pharmacies are also required to have a DEA registration, correct?

A. Yes.

Q. They're also required to renew it periodically?

A. Yes.

Q. Why is that?

A. Again, every three years so we can do background and make sure that they are indeed licensed appropriately and have not had any disciplinary action.

Q. Are you aware of any instance from your work at DEA where any one of the three distributors in this case supplied controlled substances to a Huntington or Cabell County pharmacy that was not registered with the DEA?

A. No.

Q. Are you aware of any instances from your tenure at DEA where one of the defendants supplied prescription opioids to

a DEA licensed pharmacy in Huntington or Cabell that the DEA had warned the distributor not to supply?

A. Not that I'm aware of.

Q. You talked for a bit yesterday about whether distributors should require certain information from pharmacies or not do business with them. Do you remember that?

A. Yes.

Q. Have you ever made it a condition for registration of pharmacies that in order to be registered they had to give distributors certain categories of information?

A. No.

Q. For example, did you ever say if you're going to be registered as a pharmacy, you've got to share dispensing data or doctor information with distributors?

A. No, we didn't tell them that.

Q. Did you ever tell distributors as a condition of registration that they had to get that kind of data from every pharmacy or refuse to do business with them?

A. No. That would be part of their due diligence. That's up to them.

Q. Let's talk about manufacturers. DEA must also register manufacturers for them to be able to make controlled substances, correct?

A. Yes.

Q. Manufacturers are the ones responsible for studying the safety and the benefits of prescription opioids and other medications that they make, correct?

A. Yes.

Q. And they're the ones who obtain FDA approval for new prescription opioids, correct?

A. Yes.

Q. And I'm not going to ask you too much about the FDA, but do you have an understanding that at least when it came to prescription opioids, the FDA was only supposed to approve a prescription opioid if they determine that the benefits outweigh its known and potential risks for the intended population?

MR. ACKERMAN: Objection to scope, Your Honor. This is --

THE COURT: Overruled.

BY MR. SCHMIDT:

Q. Do you want me to re-ask it?

A. The FDA's approval process is on safety and efficacy.

Q. And they've got to determine that the safety -- that the benefits outweigh the risks, right?

A. I believe that's built into it, safety and efficacy, yes.

Q. Are you aware that the physician warnings that manufacturers were required to provide for the prescription

opioids warned doctors that they had a risk of abuse and addiction?

A. In the literature? I'm sure it's in there, yes.

Q. Are you aware of any distributor in this case that distributed opioids in Huntington or Cabell that were not approved by the FDA?

A. I'm not aware of any.

Q. Are you aware of an instance where the DEA ever told a distributor in this case not to do business with the DEA registered manufacturer?

A. I -- I don't have any information on that.

Q. Okay. Let me ask you just a few more questions on distributors and then I'll turn to a different topic.

Distributors aren't authorized to write prescriptions, correct?

A. That's correct.

Q. They don't evaluate a patient's legitimate medical need for opioids in terms of deciding whether the opioids are appropriate for that patient, correct?

A. That's correct.

Q. They can't second-guess legitimate medical decisions by prescribers, correct?

A. I don't understand when they would be questioning a legitimate medical prescription.

Q. And they don't have access to individual patient

medical records because of privacy laws, correct?

A. They wouldn't have access to that.

Q. There's been discussion in this case about a term "know your customer's customer". That's not a term you were familiar with during your time with DEA, correct?

A. No. "Know Your Customer", not "Know Your Customer's Customer".

Q. You recognize that distributors play an important role in insuring an adequate and uninterrupted supply of prescription opioids?

A. Yes.

Q. It's important -- it's an important role in terms of them being able to move those drugs downstream and ensure that pharmacies and hospitals have those drugs, correct?

A. Yes.

Q. And that's important because if a patient doesn't get the medication they need, there's a breakdown in the system, correct?

A. Yes.

Q. And that role is a similar role, or a similar interest, a similar purpose, to the DEA in ensuring an adequate supply, correct? Distributors are part of that process of ensuring an adequate supply?

A. Yes.

Q. You agree that it's critical for patients who have a

medical need for prescription opioids to have access to them?

A. Yes.

Q. A couple small points. During your ten years at DEA, you never told distributors to retain due diligence files on all of their customers for all time, correct?

A. I personally did not, no.

Q. You can't identify anyone at DEA who told that to distributors, correct?

A. No. It's just common sense that if they're doing due diligence and they're maintaining files, they would maintain files for the duration of that customer's business relationship so they could see and reach back and look at what the prescribing patterns were from the beginning all the way up to the present.

Q. While you were at DEA you recognized that ARCOS data was helpful to the agency in generating leads for investigations, correct?

A. Yes.

Q. Registrants requested ARCOS data from DEA, but DEA declined to share it, correct?

A. Yes. We were -- we were instructed that we could not share it, yes.

Q. Do you know that DEA has not been required to give distributors limited access to ARCOS?

them in awhile, so --

Q. Do you take any issue with the fact that the number of DEA registrations issued to pharmacies in West Virginia went up by about a hundred between -- or 20 percent between 2005 and 2015? Do you take any issue with that?

A. I wouldn't know.

Q. Okay. Well, let me show you then.

MR. SCHMIDT: And may I approach, Your Honor? Two single page documents.

BY MR. SCHMIDT:

Q. Mr. Rannazzisi, Exhibit MCWV-2183 is a printout from the Diversion Control Division Registration -- Registrant Population by State and Business. Do you see that?

A. Yes.

Q. And it allows you to select a state that that box that says West Virginia and it allows you to select a time period. It looks like we actually chose later, August -- August, 2006. Do you see that?

A. Yes.

Q. And there's 513 DEA registered pharmacies. Do you see that?

A. Yes.

Q. And 5,446 DEA registered practitioners. Do you see that?

A. Yes.

Q. If you go to the next slide, or the next document, MCWV-2197, it's the same web page, also for West Virginia, this time for October, 2015. And do you see that the pharmacies have gone from 513 to 600, nearly a hundred?

A. Okay.

Q. And that practitioners have gone from 5,446 to 6,656, more than a thousand? Do you see that?

A. Yes.

MR. SCHMIDT: We'd move these two into evidence, Your Honor.

THE COURT: Any objection?

MR. ACKERMAN: No objection.

THE COURT: They're both admitted.

BY MR. SCHMIDT:

Q. My question on this to you simply is I take it your judgment at DEA was that that increase in both pharmacy and doctor registrations both by somewhere in the order of 20 percent was appropriate given medical needs and legitimacy of those pharmacies --

THE COURT: Let me interrupt and ask you a question. What's a mid-level practitioner on that chart?

THE WITNESS: Your Honor, that would be a physician's assistant, advanced practice nurse, and certain -- podiatrists.

THE COURT: And they're authorized under some

circumstances to prescribe opioids?

THE WITNESS: Yes, sir. The way -- the way that the Controlled Substances Act works is we look to the State. If the State grants them the ability to prescribe controlled substances, we're required -- unless they have some kind of felony in their background, we're required to give them a license.

BY MR. SCHMIDT:

Q. And just to complete the record, that category for mid-level practitioners, more than doubled from 910 to 2,023, correct?

A. Yes.

Q. I take it you had view that this growth in registrations from mid-level practitioners, practitioners and pharmacies was appropriate?

A. Well, the State dictates the practice of medicine, the practice of pharmacy, and the oversight of the mid-level. So it's what the state believes is appropriate, not what DEA believes.

Q. Well, in terms of DEA granting them a separate registration, did DEA believe it was appropriate to separately register them under its standards?

A. As long as they met the appropriate licensure requirements under the State, DEA has really no choice but to -- to register them.

Q. I want to focus on -- we -- you and I talked earlier about the .01 percent of the doctors that DEA takes action against on an annual basis. Yesterday you were asked about 16,000 doctors. Do you remember that testimony?

A. Yeah. I think it was a range, but --

Q. Yeah. You agree that it's a good thing to require DEA criminal background investigations of all new registrant applications, correct?

A. There should be a background investigation done, yes.

Q. There was a period of time where you didn't do any background checks either with the initial registration of a prescriber or subsequent registration of a prescriber, correct?

A. There was a time where we -- there was a time where we were not given access to certain databases and we had to go through private -- private means to get that background information, yes.

Q. Well, I think that's a little different than what I asked. Let me try one more time.

Did there come a point in time where you didn't do any background checks either with the initial registration of a prescriber or a subsequent registration of a prescriber? Yes or no, if you can?

A. I don't recall. I -- I know there was a time where there was an issue with that. I just don't recall the exact

time and the length of that time.

Q. Can we cull up the July 16th, 2020 transcript at Page 129, Lines 2 through 7?

MR. ACKERMAN: For the record, Your Honor, we'd renew our objection to use of this transcript, which is not the MDL transcript.

THE COURT: All right. Overruled.

BY MR. SCHMIDT:

Q. Question, then there came a point in time where you didn't do any background checks, either with initial registration of a prescriber or subsequent registration of a prescriber, correct? And your answer was no. We relied on the State. Did I read that correctly?

A. Yes. And I said we relied on the State, but there were other things that occurred, but that's -- that's absolutely correct. We did rely on the State.

Q. And you're aware of government findings from after your watch that you relied on the good faith of applicants to disclose relevant information, correct?

A. Yes.

Q. And that's a true statement, that you relied on the good faith of applicants to disclose relevant information, correct?

A. And the State, yes.

Q. Do you know with specificity what types of background

checks West Virginia did?

A. I don't know.

Q. Let me ask you, does prescriber registration from the DEA, in your view, provide meaningful protection to the public against improper prescribers?

A. Yes.

Q. Let's go to the second category, investigations. Do you know there are times where distributors told the DEA they were cutting off pharmacies, correct?

A. I'm sorry. Can you repeat, please?

Q. Of course. Do you know there are times, occasions, when distributors told the DEA that they were cutting off pharmacies, correct?

A. Yes.

Q. And of the instances where that happens, you don't know what percentage of those pharmacies DEA actually investigated, correct?

A. No. As I sit here, no.

Q. You can't tell me if it was 10 percent, 50 percent, 1 percent, correct?

A. I don't know.

Q. You can't tell me what percentage of the tens of thousands of suspicious orders that DEA received on your watch that actually directly led to an investigation, correct?

A. I don't -- I don't know and I don't think I could -- I don't think I could tell you that even if I did know.

Q. Okay. I'll stand on your you don't know. Do you know whether it was more than one percent of suspicious orders reported that resulted in an investigation? Do you know?

A. I don't know.

Q. Okay. Can you identify any suspicious orders reported for pharmacies in Huntington or Cabell? And I don't want you to tell me which ones, but can you any that resulted in investigations?

A. I don't know.

Q. You're aware that DEA has been criticized for its use of Suspicious Order Reports that have been submitted by distributors, correct?

A. Could you repeat that, please?

Q. Are you aware that DEA has been criticized by the Office of the Inspector General for its use of suspicious orders submitted by distributors?

A. Can you tell me which report you're referring to? Is that the 2019 report?

THE COURT: Just a minute.

Mr. Ackerman?

MR. ACKERMAN: Actually, let the witness clarify first because I think that will explain my objection.

THE COURT: All right.

THE WITNESS: 2019 report?

MR. SCHMIDT: Yes.

MR. ACKERMAN: All right. So, Your Honor, counsel is now beginning to question regarding a 2019 Office of the Inspector General Report. That report was issued after the MDL deposition. It was not addressed in the MDL deposition. So, we'd offer our scope objection consistent with your ruling on the permissible scope of Mr. Rannazzisi's testimony with respect to this line of questioning.

MR. SCHMIDT: It relates to his tenure, sir.

THE COURT: Pardon me?

MR. SCHMIDT: It relates to his tenure, Your Honor.

THE COURT: Yes. Overruled. This is cross examination. I'm going to allow it.

By MR. SCHMIDT:

Q. Are you aware of that 2019 report that takes issue with how DEA dealt with Suspicious Order Reports on your watch?

A. I remember there was a section in there about suspicious orders, yes.

Q. And one of the findings from that report, do you recall, is that DEA Field Division staff did not receive access to the Suspicious Order Reporting System until 2017, after your tenure; do you recall that?

A. No. I -- if you can --

Q. Of course.

A. I would like to read that.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: This is in evidence.

MR. FARRELL: Judge, on behalf of Cabell County and to save us some time, does this open the door for re-direct on this document with this witness?

THE COURT: Well, we'll cross that bridge when we get to it, Mr. Farrell.

MR. FARRELL: Thank you.

BY MR. SCHMIDT:

Q. And do you recognize this document as the one we've been discussing?

A. Yes.

Q. And if you look on Page 36, it says in the middle paragraph five lines, six lines, seven lines down, one diversion program manager.

MR. SCHMIDT: Can you highlight that language from the middle paragraph, please?

BY MR. SCHMIDT:

Q. Described the SORS database as a "joke", noting that DEA Field Division staff did not receive access to the SORS database until 2017, nearly ten years after it was created. Are you aware of that finding?

A. I'm sorry. Which page are we on here?

Q. It's little numbered Page 36.

A. 36?

Q. In the lower left. Were you aware of that finding, sir?

A. Yes. That was from one diversion investigator, one diversion program manager, who said that.

Q. Your understanding is that when there was follow-up on Suspicious Order Reports it would be done by the local Field Office agents, correct?

A. Yes.

Q. Are you aware of any suspicious orders -- well, I think I probably asked this.

Let's move to the next category. And I'm actually going to jump to number 4, regulations and guidance.

Could we cull out P-34, which is a copy of your 2007 letter? And I'm just going to point you to specific language. If we go to the second paragraph of your letter and the second last sentence. Accordingly, DEA does not approve -- wrong sentence. The one before, please.

Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Do you see that?

A. Yes.

Q. That was your view throughout your tenure at DEA,

correct?

A. Yes.

Q. Are you aware of any of your predecessors stating that view in writing in a document you could point us to?

A. I -- I don't -- I can't recall if there was or was not.

Q. Now, let me focus on your watch, 2005 to 2015. I believe you've covered this, but I need to make sure I've covered it. On your watch you made clear that how a distributor created a Suspicious Order Monitoring System was for them to figure out, correct?

A. They were required to create their own system, yes.

Q. You refused to approve individual suspicious order monitoring systems, correct?

A. We weren't authorized to approve suspicious order monitoring systems.

Q. While you were at the DEA you took the position that it was up to the distributors to figure out whether an individual order was suspicious or not, right?

A. It was up to the distributor to determine what's suspicious and what's not.

Q. You took the position that it was up to the distributor to figure out whether to ship an order or not, correct?

A. That's correct.

Q. And you took the position that it's up to the distributor to figure out whether to increase thresholds for